ABSTRACT

Methods and kits are provided for predicting the response of patients with B-cell chronic lymphocytic leukemia (CLL) to treatment with agents that bind to the CD20 and CD 52 antigens on the surface of B lymphocytes. The methods of the present invention are for identifying patients who are refractory and patients who are responsive to therapy with such agents by analyzing the genome of cells obtained from the patients for the presence of specific chromosomal abnormalities, including del(17p13.1), and one or more of del(13q14.3), del(11q22.3) and trisomy 12. The methods are performed using appropriate cytogenetic analysis techniques, such as fluorescence in situ hybridization (FISH), with probes capable of detecting the specific cytogenetic abnormalities. Patients without del(17p13.1) but with del(13q14.3), del(11q22.3) or trisomy for chromosome 12, have been shown to be responsive to agents that bind CD20, such as rituximab. Patients with del(17p13.1) have been shown not to be responsive to rituximab, but are responsive to agents that bind CD52, such as alemtuzumab. By customizing treatment of CLL based on a patient's cytogenetic profile, an improved outcome may be achieved for the patient, along with time and cost savings that are afforded by foregoing unnecessary therapy.